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| 50670 DAVIS WRIC | 7590 08/24/201 HT TREMAINE LLP/ | EXAM | EXAMINER | |
| 865 FIGUEROA STREET SUITE 2400 LOS ANGELES, CA 90017-2566 | | | NGUYEN, HIEN NGOC | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentlax@dwt.com sethlevy@dwt.com

Application No. Applicant(s) 10/567,248 JO ET AL. Office Action Summary Examiner Art Unit HIEN NGUYEN 3768 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 June 2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 16-24 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed.

6)⊠ Claim(s) <u>16-24</u> is/are rejected.
7)□ Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on <u>02/06/2009</u> is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | |
|--|--|--|--|--|
| a) All b) Some * c) None of: | | | | |
| Certified copies of the priority documents have been received. | | | | |
| Certified copies of the priority documents have been received in Application No. | | | | |

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

| Attachment(s) | |
|--|--|
| 1) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Minformation Disclosure Catenanan(s) (PTO/65/08) Paper No(s) Mail Date <u>08/09/2010</u> | 4) Interview Summary (PTO-413) Paper No(s)Mail Date. 5) Aktics of Informal Patent Application. 6) Other: |
| S. Petent and Transarian Office | |

Art Unit: 3768

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The method step of Laguerre deconvolution to estimate the IRF at every pixel of the data is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Deconvolution is needed in order to estimate the IRF then expand the IRF. A short excitation pulse and of a single exponential fluorescence decay can not often be fulfilled in practice therefore deconvolution algorithm needs to be applied. Further, because fluorescence lifetimes in imaging are determined on a pixel-by-pixel basis, iterative methods for recovering the time decays can be time consuming and generally require the acquisition of a considerable number of data samples (see applicant's specification page 3, lines 1-12 and Fig. 8).
- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3768

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Does the step of expanding come before estimating? According to Fig. 8, it is estimating the expansion coefficient? What is the applicant try to claim? Is fluorescence decay function the same as fluorescence impulse response function? According to the specification they are the same. Examiner suggests delete fluorescence decay function to avoid confusion.

Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcu et al. (US 6,272,376), in view of Maarek et al. (Time-resolved Fluorescence Spectra of Arterial Fluorescent Compounds: Reconstruction with the Laguerre Expansion Technique (provided in IDS)) and further in view of Siegel et al. (Studying

Art Unit: 3768

biological tissue with fluorescence lifetime imaging: microscopy, endoscopy and complex decay profiles (provided in IDS)).

7. Addressing claim 16. Marcu discloses obtaining a plurality of images of a measured fluorescence intensity decay for sample having been exposed to an excitation, pulse generated by an excitation source, the measured fluorescence intensity decay being associated; with a fluorescence decay function and/or a fluorescence-impulse response function (see col. 4, lines 28-54, col. 8, 20-54, using light to obtain images and using Laguere deconvolution to obtain fluorescence impulse response function); expanding the fluorescence decay function and/or the fluorescence impulse response function on a Laguerre basis (see col. 4, lines 28-54). However, Marcu does not disclose detail Laguerre expansion coefficients for each pixel of a plurality of pixels in the images. In the same field of endeavor, Maarek discloses: estimating a plurality of expansion coefficients ("{c_i}") within the Laguerre basis (see pages 180-181); generating a map of each of the plurality of expansion coefficients ("{c₀}") (see pages 179-181); and computing a map of average lifetimes by constructing an impulse response function ("IRF") for a predetermined number of time instances and interpolating a time point at which the IRF becomes 1/e of its maximum value, wherein the IRF is represented by the equation; h(r, n) (see materials and methods section pages 179-180 and results section pages 180-181). In the same field of endeavor, Siegel discloses fitting exponential decay function to each image pixel and generate a FLIM map of fluorescence lifetime (see page 2998). It would have been obvious to one

Art Unit: 3768

of ordinary skill in the art at the time of the invention to modify Marcu's method to expand coefficient using Laguerre basis at every pixel as taught by Maarek and Siegel because these method steps improve the accuracy of characterizing and discriminating biological systems (also see applicant's specification page 3, lines 10-12, fluorescence lifetimes in imaging are determined on a pixel-by-pixel basis therefore in order to get an accurate lifetime map using Laguerre expansion basis every pixel need to take into account).

8. Addressing claims 17-23, Marcu discloses wherein the sample is selected from the group consisting of a biological tissue, a chemical, a biochemical sample and combinations thereof (see col. 4, lines 1-3); detecting a physiological condition from the group consisting of a tumor and an atherosclerotic plaque (see col. 2, line 59-col. 3, line 21 and col.4, line 65-col.5, line 29); including predicting the distribution of concentration of at least one biochemical component of the sample images, wherein the sample is composed of a plurality of biochemical components (see col. 1, lines 15-29 and col. 3, line 65-col. 4, line 27, reveal both quantitative and qualitative component of protein and lipid in the sample give the distribution of concentration of each in the sample); including monitoring an intracellular component and an activity of the intracellular component (see col. 11, line 55-col. 12, 67, the method monitors and analyzes intracellular component to classify the condition of the tissue); including identifying a chemical with a biological activity for automated screening of the sample for new drugs discovery (see col. 7, lines 11-42; the method is automated by the system to perform an analysis of tissues and

Art Unit: 3768

other organic system; this analysis identifies chemical with a biological activity); further configured to characterize drugs based on their chemical composition so high speed/throughput surveying and counting of the drugs is possible; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method to characterize drugs based on their chemical composition because the method determines the qualitative and quantitative information of the organic composition (see col. 1, lines 15-60, the method characterize organic sample; this method would be efficient and accurate in characterizing drugs); configured to characterize a biochemical essay based on biochemical contents to facilitate high speed/throughput surveying/analysis of the essay; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method to characterize biochemical essay based on their biochemical content because the method determines the qualitative and quantitative information of the organic composition (see col. 1, lines 15-60). The method characterize organic sample. This method would be efficient and accurate in characterizing biochemical essay. A tissue sample is a biochemical essay.

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marcu et al. (US 6,272,376), in view of Maarek et al. (Time-resolved Fluorescence Spectra of Arterial Fluorescent Compounds: Reconstruction with the Laguerre Expansion Technique) and further in view of Siegel et al. (Studying biological tissue with fluorescence lifetime imaging: microscopy, endoscopy and complex decay profiles (provided in IDS) and Reel (US 2003/0136921).

Art Unit: 3768

10. Marcu, Maarek and Siegel do not disclose sequencing DNA microarray. Reel discloses automated sequencing DNA microarray to determine composition of the sample (see [0002]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Marcu's method to include sequencing DNA microarray as taught by Reel because DNA sequencing allow the method to determine the composition of the DNA sample such as structure and function of protein and lipid in the DNA sample.

Response to Arguments

Applicant's arguments with respect to claim 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Application/Control Number: 10/567,248

Art Unit: 3768

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./ Examiner, Art Unit 3768 /Long V Le/ Supervisory Patent Examiner, Art Unit 3768